THE SLOANE GROUP

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

RE: **Irradiation in the Production, Processing and Handling of Food (Docket No. 98N-1038)**

The Sloane Group is a management consulting firm, specializing in launching new technologies. We have been involved with assignments for Fortune 500 companies and small entrepreneurial ventures in the food safety arena for over five years. Several of our present customers have developed new technologies to improve food safety, and we are currently engaged in assisting them to raise significant capital to launch these technologies, to locate strategic partners for global commercialization or both.

We believe we have a unique perspective, having worked with meat and poultry processors, as well as solution providers. In fact, one of our principals worked in his family's pork processing facilities for twenty-one years. The food industry is extremely competitive and never before have processors been faced with so much potential liability due to unsafe product than in recent years.

We wish to respond to your proposed rule and have answered your questions as requested. The following is our comments and recommendations:

1. **Does the current radiation disclosure statement convey meaningful information to consumers in a truthful and nonmisleading manner?**

We do not believe it does. Today's consumer is more educated and aware of food safety than ever. However, many still interpret irradiation labeling as a warning. Some associate it with improved safety, but with caution. More importantly, processors still believe that the majority of the population is against irradiation and that consumers will not buy product labeled as such. What's even more misleading is the difference between what irradiation accomplishes with meat and poultry as compared to phytosanitary

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applications such as fruit. We reduce or eliminate pathogens in meat and poultry, but only prevent pests from being transported from one region to another for phytosanitary. The radiation dose required to achieve the elimination of pests is far less than what is required to reduce foodborne pathogens.

2. How do consumers perceive the current radiation disclosure statement – as informational, as a warning or as something else?

We believe some perceive it as a warning, and others as something else.

3. Does the wording of the current radiation disclosure statement cause "inappropriate anxiety" among consumers? What are examples of inappropriate anxiety"?

We feel that the current disclosure statement does cause inappropriate anxiety. For years now people have associated the words irradiation, and radioactive to mean a similar thing. Often times the first thought is one of danger or they are being warned. This isn't as prevalent as it used to be simply because more consumers are aware of the harmful foodborne diseases. Even though consumers are more educated, food processors do not believe that most consumers are educated enough about irradiation and they won't engage in irradiation technology as they should, as long as the current label practice persists. Some companies, such as spice producers who have been using irradiation for a long time, mark some spices as "not irradiated".

4. What specific alternate wording for a radiation disclosure statement would convey meaningful information to consumers, in a truthful and nonmisleading manner, and in a more accurate or less threatening way than the current wording?

Any mandatory label will cause confusion and misunderstanding. Why not allow processors to come up with their own label. If the product has been improved via radiation then it is to their benefit to call this to the consumer's attention. They'll need to do this anyway to have product differentiation so they can justify charging more for the product in order to cover their costs to irradiate.

5. Would consumers be misled by the absence of a radiation disclosure statement in the labeling of irradiated food? Are consumers misled by the presence of such a statement?

The absence of a disclosure statement will not mislead the consumer. A voluntary label will inform, not mislead the consumer.

6. With respect to foods containing irradiated ingredients, are consumers misled by the absence of a radiation disclosure statement? Would consumers be misled by the presence of such a statement?

Consumers have not been misled by the absence of a label disclosing the use of irradiated ingredients. We mentioned spices before and this is a good example. Spices that have been irradiated are used as an additive in food processing today. You ask if the consumer would be misled by the presence of such a label. We think so. Let's look at an example using spices again. Many spices are fumigated. Would the spice producer be keen to label their products, "treated with methyl bromide"? Spice producers would fear the effect on sales. We're sure the consumer would be misled as they would view this as a warning too, even though it is done to prevent disease and make the food more safe.

7. What is the level of direct consumer experience with irradiated foods that are labeled as such?

Many reports indicate that the consumer is reacting favorably to irradiated foods. The real question is by what margin. Are there really enough irradiated foods out there to truly understand this. Afterall, there is always some percentage of the population that will try new products without a second thought. If mandatory labeling persists, processors will not put irradiated product on the market in sufficient enough quantities to ever really answer this question.

8. What is the effect of the current required labeling on the use of irradiation? Does the current required labeling discourage the use of irradiation?

The current labeling practices inhibit the use of irradiation, so yes it discourages its' use.

9. What do consumers understand to be the effect of irradiation on food? For example, what do consumers understand about the effect of irradiation on the numbers of harmful microorganisms in or on food?

We believe most consumers understand that irradiation is to greatly reduce foodborne illness.

10. Do consumers readily recognize the radura logo?

No they do not at this time.

11. Do consumers understand the logo to mean that a food has been irradiated?

No, we don't think so.

12. Do consumers perceive the radura logo as informational, as a warning, or as something else?

They don't really know what it means.

13. Should any requirement for a radiation disclosure statement expire at a specified date in the future?

No. If you don't require a label in the future, why have one now.

14. If so, on what criteria should the expiration be based?

Not applicable.

15. **If the expiration of labeling requirements for irradiated foods is to be based on consumer familiarity with the radura logo and understanding of its meaning, what evidence of familiarity and understanding would be sufficient to allow these requirements to expire?**

We don't believe the general public will ever associate the logo with irradiated food. Most people think it is an advertising or branding logo.

In summary we would like to say that we believe that irradiation is just too valuable of a tool not to be used. In our experience, this technology will not be readily adopted by processors until this mandatory labeling issue is resolved. When we talk to processors they admit that irradiation is an excellent way to make the product far more safe, but they always hesitate to become involved or be the first, due to their perception of consumer perception.

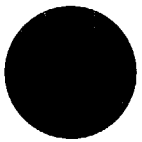
Processors will label their product in some fashion to be able to differentiate it in the marketplace. Irradiation comes at a cost to them. In order to recoup that cost they will need to pass that on to the consumer. If a consumer is going to pay more, they will need to know why. Logic and economics will drive a voluntary label.

The public very much needs irradiation. Please do what is necessary from a regulatory point of view to make this happen.

Sincerely,

Michelle McCall

Michelle McCall
Director



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